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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/898,885 | 07/03/2001 | Raghavan Rajagopalan | MRD / 62 | 2179 |

26875 7590 04/25/2003

WOOD, HERRON & EVANS, LLP
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CINCINNATI, OH 45202

EXAMINER

CEPERLEY, MARY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

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DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/898,885

Applicant(s)

RAJAGOPALAN ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 14, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,24-30,40 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 13,24-30 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) The finality of the March 03, 2003 Office action is hereby withdrawn in view of the new ground of rejection under 35 USC 112, first paragraph, set forth below. The amendment, remarks and the declaration of Dr. Rajagopalan filed April 14, 2003 have been entered and considered.

2) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as (a) containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and (b) as being based on a specification which does not contain an enabling written description of how to use the composition of claim 40.

There is no written description in the specification to support the claim 40 limitation "a pharmaceutically acceptable formulation of organic azides in an *in vivo* administrable form". The following sections of the specification relate to pharmaceutical compositions and methods for their use: page 11, lines 19-20; page 13, lines 4-6 and 22-25; page 15, lines 3-11. These portions of the specification all describe pharmaceutical compositions containing azide-dye compounds which contain a targeting moiety (i.e. the pharmaceutical compositions contain compounds wherein E is not H). There is no description of pharmaceutical compositions containing compounds wherein E = H. Neither is there any indication that the claimed compounds wherein DYE is defined as "an aromatic or a heteroaromatic radical of cyanines", *in the absence of any targeting component*, would be expected to be useful as *in*

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in vivo phototherapy agents, i.e. there is no disclosure of how the dye compounds wherein E is H would be expected to adhere to a target area appropriate for phototherapy. Although no specific utility is described for the compounds wherein E = H, it can be inferred from Fig. 2 that such compounds are intermediates for the preparation of dye-azide conjugates with targeting biomolecules. This utility as an intermediate (reactant) is clearly different from a pharmaceutical utility.

5) Claim 40 is again rejected under 35 U.S.C. 102(b) as being anticipated by each of Pochinok et al, Ol'shevskaya et al, Clecak et al, and Leung et al for the reasons of record.

Applicants' arguments filed April 14, 2003 have been fully considered but they are not persuasive. Although claim 40 is a composition claim, applicants arguments' are directed to a method of use of the composition rather than to the composition per se. The composition *per se* is described in the prior art as discussed in the previous Office actions i.e., the prior art describes the claimed azide-dye compound in solvents which would be appropriate for pharmaceutical utility. In order to be anticipatory, the prior art need not disclose the same intended use of the compositions, but only the compositions per se which have the same components as the compositions of the instant claim.

The Rajagopalan declaration similarly attempts to distinguish claim 40 from the prior art based on a discussion of a method of use rather than the composition *per se*. Applicants apparently do not disagree that compositions containing pharmaceutically appropriate carriers are described in the prior art. See paragraph 5 of the declaration which states that the prior art references "address only the technical feasibility of producing the formulation *without addressing the bioavailability or the chemical and physical stability*" (the italicized section addresses the method of use of the composition rather than the composition *per se*).

6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

April 24, 2003



Mary E. (Molly) Ceperley
Primary Examiner
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